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The neoV

Application Manual

1064

- Nail Fungus
- Warts

neoLaser

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In case of any doubt, please contact neoLaser before using the device.

THERAPY INDICATIONS

1. This manual covers various podiatry applications approved for use with the neoV laser; manual is designed to assist both the “beginner” and “experienced” users.
2. Clinical information detailed in this manual is intended to be used by a healthcare professional who posses relevant medical background, as well basic knowledge with medical lasers.
3. It is strongly advisable to refer to appropriate literature relevant to the intended use. If no such literature is available, please contact your local neoLaser representative for support.
4. Laser parameters values are usually detailed with min /max values. These parameters were developed based on the extensive use of the device by healthcare professionals.
5. The user should always utilize his/her experience and knowledge, as well as clinical best practice, taking into consideration relevant patient information. Neither the author nor the manufacturer will be liable for a treatment failure caused by misuse of the device.

MANAGING UNWANTED EFFECTS

Since safety goggles must be worn throughout the procedure, the operator must be aware that his/her vision is temporarily altered (color shades appear differently, contrast may be dimmed, etc.) - this can lead to visual misjudgment. It is than recommended from time to time to turn off the laser, remove the goggles and inspect the treated area without goggles.

In case of any eye injury due to disregard of the eye protection by safety goggles, an ophthalmologist hast to be consulted.

Laser radiation can cause immediate and unwanted tissue damage, therefore it is highly advisable to have within reach measures for burn control (such as: ice or cooling pads, topical products, special dressings for burns, etc.).

Laser radiation can cause unwanted hemostasis and coagulation damages. The extent strongly depends on the exposure time to the laser’s radiation.

Coagulated tissue is not harmful and normally will not cause issues. In case of overheating of temperature-sensitive areas, applying immediate cooling should be done and treatment should be stopped and reevaluated.

LASER RADIATION & TEMPERATURE EFFECT	
TEMPERATURE	EFFECT
> 40° C	Enzyme induction, membrane disaggregation, edema
45° – 65° C	Tissue damage, irreversibility depends on irradiation time
> 65° C	Coagulation
> 100° C	Dehydration
> 150° C	Carbonisation

Discomfort from the heating which is generated by the laser may occur. To avoid this, the user should follow the application parameter guidelines. If possible, cooling can reduce patient discomfort during and after treatment.

The neoV laser produces an intense, highly directional beam of light. If directed, reflected, or focused upon an object, laser light will be partially absorbed, raising the temperature of the surface and/or the interior of the object, potentially causing an alteration or deformation of the material and can also cause tissue damage. Moreover, this beam of light can be hazardous to the eye even when the laser light is reflected from a different surface.
The energy generated by the neoV1064 laser is in the infrared portion of the electromagnetic spectrum.

Warning/Hazard labels found on the NeoV Laser device

Infrared lasers are particularly hazardous, since the body's protective "blink reflex" response is triggered only by visible light. In this sense, people exposed to high power laser emitting invisible 1064 nm radiation, may not feel pain or notice immediate damage to their eyesight. A pop or click noise emanating from the eyeball may be the only indication that retinal damage has occurred i.e. the retina was heated to over 100 °C resulting in localized explosive boiling accompanied by the immediate creation of a permanent blind spot.

Lasers are categorized and classified into 4 classes, ranging from Class 1 to Class 4. The neoV is a Class 4 laser, which is the highest and most dangerous class of laser. By definition, a class 4 laser can burn the skin, or cause devastating and permanent eye damage as a result of direct, diffuse or indirect beam viewing. These lasers may ignite combustible materials, and thus may represent a fire risk. These hazards may also apply to indirect or non-specular reflections of the beam, even from apparently matte surfaces—meaning that great care must be taken to control the beam path and to protect the eyes of any person within the laser use area.

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BASIC LASER SAFETY INSTRUCTIONS

To avoid any injuries it is important to follow the laser safety instructions:

- **Operating personnel –** the neoV laser system can be operated by authorized personnel only.
- **Laser Safety Goggles** – Laser safety goggles are crucial for the safety of all persons in the laser use area. Make absolutely sure that before turning the laser to READY mode (Yellow indicator on user screen and Yellow light on diagonal stripe on top of laser), every person in the area that may be impacted by laser radiation is wearing laser safety goggles. Make sure that the goggles are suitable for eye protection from the neoV laser radiation (see User Manual for further information). This includes all persons in the laser treatment area or laser room, including patient, physician, nurse, general staff and anyone in the vicinity of the treatment area.
- **Training** - all users of the neoV laser system have to be trained by neoLaser authorized personnel or by your trained authorized dealer.
- **Laser Warning Symbols** – laser Warning Symbols must be clearly placed in all areas where the laser system is used.
- **Laser Operating Area** – the laser operating area should be clearly marked and sealed while laser is in operation. All personnel should be aware when the laser is operating and should not enter the Laser Operating Area without adequate safety protections while the laser is in use.
- **System Check** – before use, verify that the system and all its components work as intended. If the system does not come up, you may try to isolate the problem, as explained in the neoV User Manual. If problem persists, contact your local authorized dealer for technical support. If any of the components are deemed malfunctioning – do not use the system, and contact your local dealer.
- **Fiber Delivery** - the fiber spot, which is illustrated by the aiming beam should always be round and well defined no scattering should occur.
- **Defined Application** – do not use the laser for any application other than its defined application, as stated in this application manual. The laser must be used only for the defined application; never illuminate/irradiate any other material or tissue besides the intended use.
- **Reflected laser radiation** - reflected laser radiation can cause the same harm as direct application, therefore you should make sure to avoid irradiating reflecting materials.
- **Standby Mode** – the neoV laser should be in Standby mode whenever the laser is not in use, e.g. during operation breaks or at the end of the surgery/procedure.

Rear Panel/Sockets

Do not connect unauthorized USB sticks into the unit, use only neoLaser supplied sticks.

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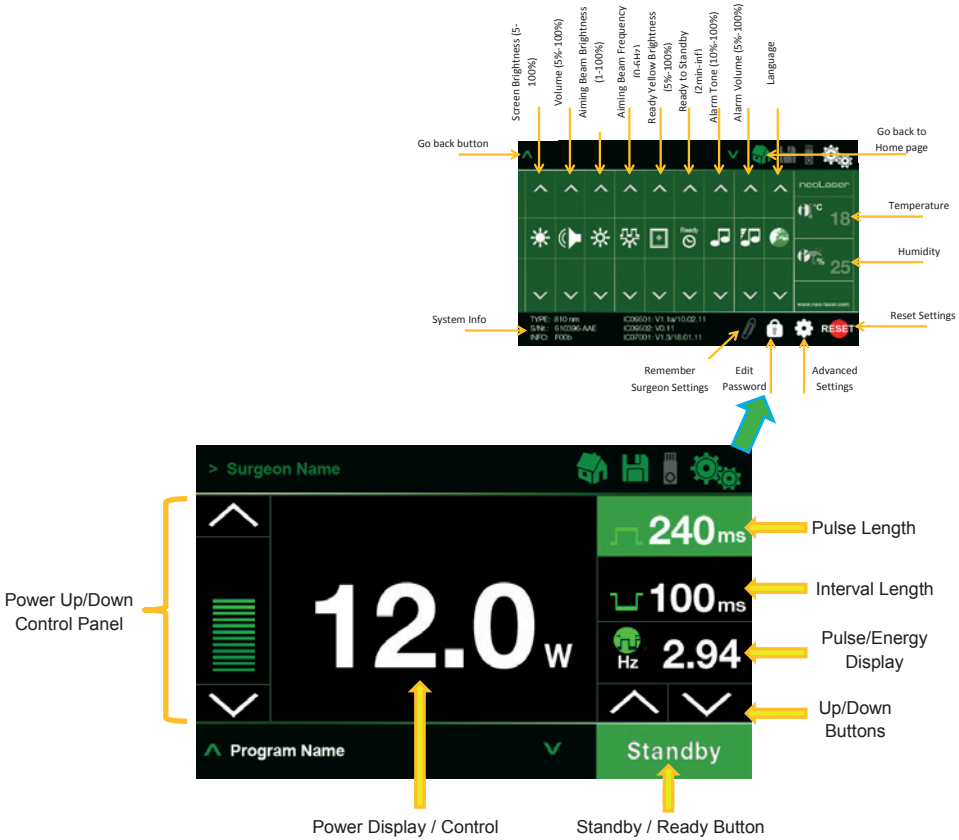


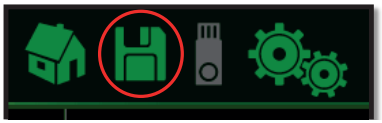
The icons and display parameters of the Main Menu are provided in the image above. The power setting of the laser is provided in the center of the screen, and corresponds to the peak power output from the fiber distal end to the tissue in Watts. On the right hand side you may read (1) the Pulse Interval which dictates the length of each pulse, or CW for Continuous Wave; (2) the Interval Length, which dictates the off time between consecutive pulses, or SP in case of a Single Pulse transmission; (3) the Energy Display which can be toggled to show 4 different parameters of dosage.
On the top line you may see the current Program selected, as well as Home, Save and Settings icons. On the bottom line you may see the Surgeon selected, and the Laser Status indicator on the bottom right hand corner showing whether the laser is in Standby or in Ready mode.

Changing Parameters

You may change the Peak Power setting as well as the Pulse Length and Interval Length on the main menu by (1) clicking on the parameter to activate its control and (2) clinking on the corresponding arrows to change it. When clicking the parameter it will be highlighted in Green to indicate it may be now changed.

Saving Parameters

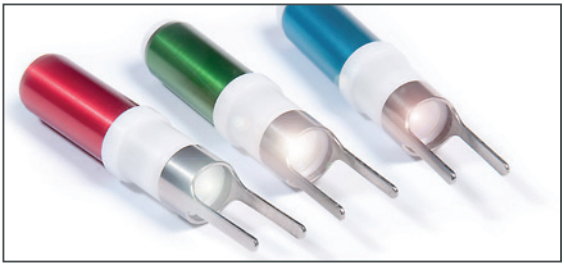
After changing parameters, the changes may be stored under the program name by clicking the Save icon on the top right hand side.



You may notice that once saved the Save icon will become inactive until a change is made. Once a parameter is changed, the Save icon will again activate to allow saving of the new parameters.

OPTICAL HANDPIECES

The optical hand pieces (Blue, Red, Green and Silver) are used for focusing/ parallelization the laser beam for different applications. They work only with the double sided fiber connector OF-WFST400-D.



HP-FOC1, HP-FOC2, HP-FOC3

HP-NF

OPTICAL HANDPIECES - SPOT SIZE Ø	
Handpiece	with OF-WFST400-D [400µm]
Blue	Ø 0.5 mm
Red	Ø 1.0 mm
Green	Ø 2.0 mm
Silver	Ø 3.0 mm

OF-WFST400-D [400 µm]

User has wide selection of hand pieces to achieve the proper spot size and power density on the target tissue from 0.5 to 3mm

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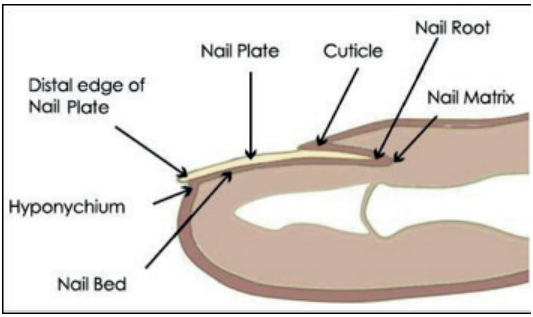
NAIL FUNGUS

Nail fungus (onychomycosis) is the most common nail disease, impacting 6-8% of the adult population. In the past, nail fungus was treated by medication, but this requires months of intake, it is expensive and has severe risk of liver damage. Using the neoV laser allows for effective treatment with no medication.

The neoV1064 produces a high intensity laser beam at 1064nm (near infrared) which goes through the nail, penetrates the nail plate, heats up the nail bed and destroys the fungus (pathogens) with minimal pain. The heat affects the pathogens by warming the cells, destroying the cell walls and thus killing the affected cells. The neoV radiation does not have any effect on the nail itself, the cuticle or the surrounding skin. At the end of the process, the nail fungus is eradicated and there is visible increase in nail clearness.



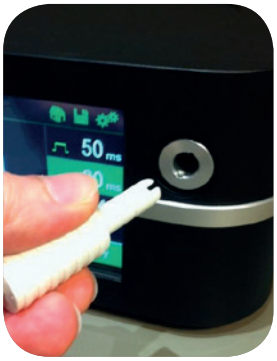
CONTRA INDICATION

This treatment is not indicated for:

- Patients suffering from neuropathy, (including diabetics with neuropathy)
- Patients with inflamed tissue around the fungus / treatment area
- Patients with hyperkeratosis infection

SETUP

The neoV1064 system should be equipped with a dual connector fiber (400 micron OF-WFST400-D) and a focusing hand piece (HP-FOC2, or HP-NF depending on physician preference). Laser should be operated and fiber and hand piece connected according to User Manual instructions (see DHF-001-R-003 neoV User Manual).



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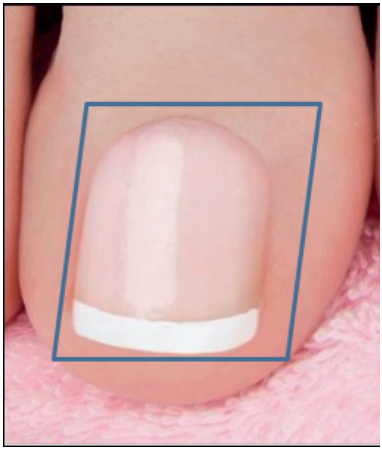
TREATMENT PARAMETERS

The duration of the treatment depends on the size of the nails, the number of nails to be treated, the laser settings, the speed of the movement, and the tolerance of the specific patient to pain.

- Apply laser dosage to all nails, as to ensure optimal results and avoid reinfection due to untreated nails.
- Scan each treated nail at least twice in each treatment session.
- Scan the laser beam continuously over the nail to ensure uniform deposition of energy on the entire nail surface as well as nail edge and surrounding tissue. Move over the nail both in horizontal and vertical movements.
- Pass over the complete nail, including the nail plate, nail wall and eponychium.
- If using HP-NF, the laser beam should be kept at a distance of ~1cm from the nail, and with a spot size of ~3mm. If using HP-FOC2, the metal distance setting prongs should be in contact with the nail ensuring spot size of 1mm on the nail
- If using a Continuous Scan Mode (high pulse rate of 30 pulses per second) – use HP-FOC2 and scan the nail in a uniform speed continuously. Do not stop in one spot. Keep motion at >2mm/sec.
- In using a Discrete Scan Mode, (low pulse rate of 2 pulses per second) – use HP-NF and move at least half a spot size between consecutive pulses.



Below are the settings recommended for both techniques. The user should choose his preferred technique based on his experience as well as patient preference.

LASER SETTINGS FOR USERS USING CONTINUOUS SCAN MODE					
Nail Size	Power (W)	Pulse ON (ms)	Pulse OFF (ms)	Total Energy [J]	Time [Sec]
Small Toe	10	20	10	150-250	20-35
Middle Toe	10	20	10	300-500	45-75
Big Toe	10	20	10	600-800	90-120

LASER SETTINGS FOR USERS USING DISCRETE SCAN MODE					
Nail Size	Power (W)	Pulse ON (ms)	Pulse OFF (ms)	Total Energy [J]	Time [Sec]
Small Toe	10	200	300	150-250	20-35
Middle Toe	10	200	300	300-500	45-75
Big Toe	10	200	300	600-800	90-120

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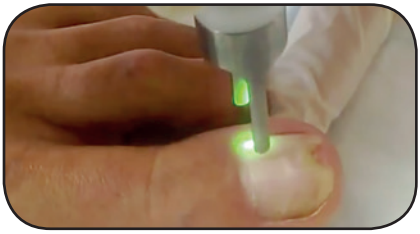
The patient will feel a heating sensation. If this sensation gets too discomforting, cease treatment for 5-10 secs. If the patient suffers from constant discomfort, turn down the power from 10W to 8W or lower.

If the patient has dark skin, it is recommended to consider taking down power as patient skin absorption may be higher due to pigments and therefore result in increased pain sensation.

Post treatment heating sensation will cease after 1-2hours.

When applying energy, you can choose to view the accumulated energy delivered to the patient, or the accumulated number of pulses delivered (on main screen below the Pulse On and Pulse Off interval times; see User Manual). In either case, it is highly recommended to record and document the dosage applied in each session. Choosing the Accumulated Energy setting will allow you to view the total dosage applied in Joules.
Please note - all personnel, including the patient, have to wear eye protection goggles; this may lead to decreased vision regarding contrast and color by the personnel and surgeon. In case of any eye injury due to disregard of the eye protection by safety goggles, immediate medical attention should be sought.



POST TREATMENT CARE

- Disinfect the hand piece by wiping it after each treatment with a special alcohol-containing disinfectant solution. Hand pieces should not be used on consecutive patients without disinfecting them first.
- The neoV laser treatment should not have side effects, when applied correctly. However, the heat generated by the laser radiation may cause patient discomfort. Post treatment, use cooling to reduce patient discomfort. Please note – discomfort may increase if laser treatment is not applied correctly. All treatments should therefore follow the above application parameters and guidelines.
- In severe cases, laser heating can cause burning of the tissue, depending on the amount of energy that is applied to the nail. This may result in burn wounds, which in extreme situations can cause necrosis. In case of overheating of temperature-sensitive areas, cool the area and use other forms of burn treatment.

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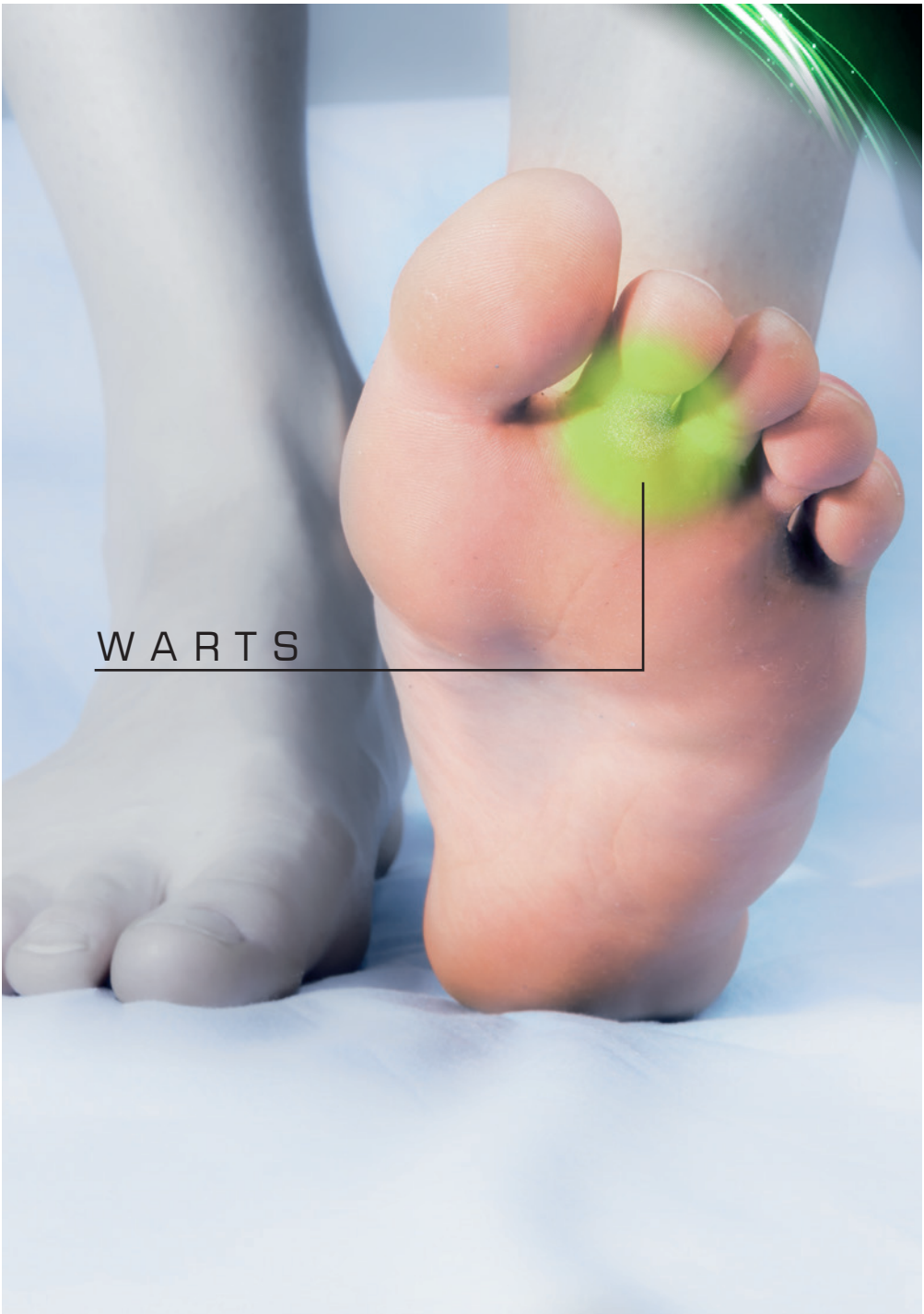
AVOIDING REINFECTION

Several key steps are recommended to reduce chance of reinfection and increase probability of successful long term outcome. These should be communicated to the patients and may include:

- Exchange regular shoes into new shoes
- Place shoes in the freezer overnight to kill any remaining fungal infection
- Use clean socks on daily basis
- Wash socks only at temperatures of >60° C to kill any remaining fungal infection
- Use antifungal powder in your socks/shoes on daily basis, or use of antifungal cream
- Wear absorbent socks (no synthetic material)
- After showering, dry the feet especially between the toes
- Wear well ventilated shoes
- If you run frequently, spray or powder on daily basis with fungicide

The patient should be followed up and examined 4-6 weeks after the last laser treatment to evaluate progress of clear nails. In any case of concern regarding outcome an additional laser session, identical in nature to the sessions described above should be considered. Final outcome and increase in clear nails can be viewed within 9-12 months of first treatment.



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BACKGROUND

Warts are benign (not cancerous) skin growths that appear when a virus infects the top layer of the skin. Viruses that cause warts are called human papillomavirus (HPV). You are more likely to get one of these viruses if you cut or damage your skin in some way.

Wart viruses are contagious.

Warts can spread by contact with the wart or something that touched the wart.

Warts that develop on the foot are commonly referred to as plantar warts.

Plantar warts have these traits:

- Grow most often on the soles (plantar surface) of the feet
- Can grow in clusters (mosaic warts)
- Often are flat or grow inward (walking creates pressure, which causes the warts to grow inward)
- Can hurt, feels like you have pebbles in your shoe
- Can have black dots

Source: American Academy of Dermatology

PREREQUISITE

- Review User Manual for all safety and system operation topics prior to using the unit
- Ensure all users wear safety goggles per requirements of User Manual and that treatment room is properly marked and protected
- Setup laser system, fiber, and hand piece per User Manual requirements (see also page 12 above for Nail Fungus setup)
- This application is applicable to neoV1064 (Part Number LSV1064-20) lasers only with up to 20Watts of power

PATIENT/SETUP

- Document the treatment area prior to treatment for clinical reference
- Debridement of the area for improved laser transmission is recommended; use disinfected instruments
- Topical and/or local anesthetic may be used to increase patient comfort
- Gel is not to be used
- Smoke evacuation and laser plume masks highly recommended

TREATMENT

Settings should be

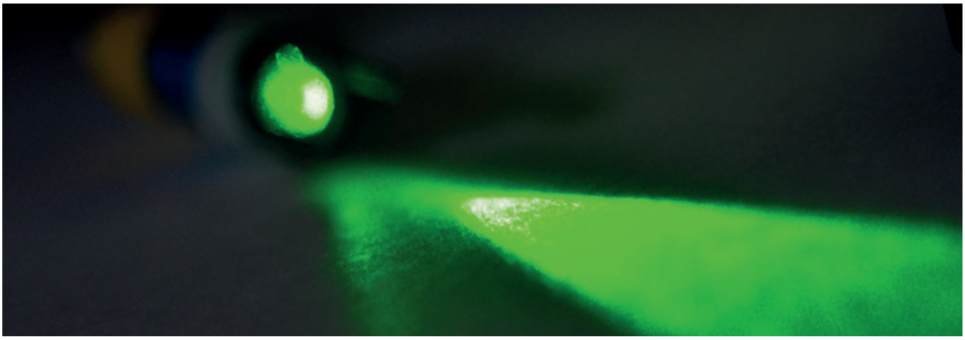
- 1mm spot size red focusing hand piece
- For skin types I-IV:
  16 Watts, 200-300 msec Pulse On,
  300 msec Pulse Off,
  total Fluence: 200-240 J/cm²
- For skin types V-VI:
  12 Watts, 150-250 msec Pulse On,
  300 msec Pulse Off,
  total Fluence: 120-150 J/cm²

Treat the entire wart area

- Make sure pulses overlap slightly
- Cover the wart area and a 1mm margin around the wart
- Endpoint: Dusky, ashen or blanched appearance to the wart with a halo or round red circle around the edge

POST TREATMENT

- Immediate cooling of the area with frozen gel pack may help patient comfort. Burn sensation may be felt up to 12 hours post treatment
- If blistering occurs, wound healing treatment should be implemented, including potential topical antibiotic or soothing ointment
- Warts will usually present a black or crusty appearance within 24 hours, a blood blister may form within 7-10 days, then crusting and sloughing off within 2 weeks
- The area should be kept clean, patient should use new shoes and socks and wash the area thoroughly
- More than one treatment may be necessary if wart persists.
  Treatments should be performed 3-4 weeks apart



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